

Appl. No. : 10/009,916
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AMENDMENTS TO THE CLAIMS

1. **(Previously presented)** An isolated or recombinant immunogenic polypeptide comprising a *Lawsonia spp.* SodC Polypeptide, a variant, or a truncated variant thereof, wherein said variant or truncated variant mimics or cross-reacts with a B-cell or T-cell epitope of *Lawsonia spp.* SodC Polypeptide.

2. **(Previously presented)** The isolated or recombinant immunogenic polypeptide of claim 1 wherein said polypeptide elicits the production of antibodies against *Lawsonia spp.* when administered to an avian or porcine animal.

3. **(Previously presented)** The isolated or recombinant immunogenic polypeptide of claim 1 which confers a protective immune response against *Lawsonia spp.* when administered to an avian or porcine animal.

4. **(Previously presented)** The isolated or recombinant immunogenic polypeptide of claim 1 wherein the *Lawsonia spp.* is *L. intracellularis*.

Claim 5 (Cancelled)

6. **(Previously presented)** An isolated or recombinant immunogenic polypeptide comprising:

(i) a peptide, oligopeptide or polypeptide comprising an amino acid sequence which has at least about 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 1; or

(ii) a peptide, oligopeptide or polypeptide which comprises an amino acid sequence having at least about 50% sequence identity to amino acid residues 1 to 42 of SEQ ID NO:1; or

(iii) a homologue or derivative of (i) or (ii) which mimics a B-cell or T-cell epitope of a *Lawsonia spp.* SodC polypeptide.

7. **(Previously presented)** The isolated or recombinant immunogenic polypeptide of claim 6 wherein said polypeptide elicits the production of antibodies against *Lawsonia spp.* in a porcine or avian animal.

8. **(Previously presented)** The isolated or recombinant immunogenic polypeptide of claim 6 wherein said polypeptide confers a protective immune response against *Lawsonia spp.* in a porcine or avian animal.

Claim 9 (Cancelled)

Appl. No. : 10/009,916
Filed : August 13, 2002

10. (Previously presented) The isolated or recombinant immunogenic polypeptide of claim 8, wherein said protective immune response is induced in a porcine animal.

11. (Previously presented) The isolated or recombinant immunogenic polypeptide of claim 6 wherein the *Lawsonia spp.* is *L. intracellularis*.

Claim 12 (Cancelled)

13. (Previously presented) The isolated or recombinant immunogenic polypeptide of claim 6 comprising the amino acid sequence set forth in SEQ ID NO: 1 or the amino acid sequence encoded by the SodC-encoding nucleotide sequence of pALK14 (ATCC 207155).

14. (Previously presented) The isolated or recombinant immunogenic polypeptide of claim 13 consisting essentially of the amino acid sequence of SEQ ID NO: 1 or the amino acid sequence encoded by the SodC-encoding nucleotide sequence of pALK14 (ATCC 207155).

Claim 15-16 (Cancelled)

17. (Previously presented) The isolated or recombinant immunogenic polypeptide of claim 6 comprising amino acid residues about 1 to about 42 of SEQ ID NO:1 wherein said polypeptide elicits the production of antibodies against *Lawsonia intracellularis* when administered to an avian or porcine animal.

18. (Previously presented) The isolated or recombinant immunogenic polypeptide of claim 17 that consists essentially of about amino acid 1 to about amino acid 42 of SEQ ID NO: 1.

19. (Previously presented) The isolated or recombinant immunogenic polypeptide of claim 17 which induces a protective immune response against *Lawsonia intracellularis* in a porcine or avian animal.

20. (Previously presented) The isolated or recombinant immunogenic polypeptide of claim 19 which induces a protective immune response against *Lawsonia intracellularis* in a porcine animal.

21. (Previously presented) A vaccine composition for the prophylaxis or treatment of infection of an animal by *Lawsonia spp.*, said vaccine composition comprising an effective amount of an immunogenic component comprising an isolated or recombinant polypeptide having at least about 70% sequence identity to the amino acid sequence set forth in

Appl. No. : 10/009,916
Filed : August 13, 2002

SEQ ID NO: 1 or at least about 50% sequence identity to amino acid residues 1 to 42 of SEQ ID NO:1 or an immunogenic homologue, or derivative thereof which is immunologically cross-reactive with *Lawsonia intracellularis*; and one or more carriers, diluents or adjuvants suitable for veterinary or pharmaceutical use.

22. **(Previously presented)** The vaccine composition according to claim 21 wherein the *Lawsonia spp.* is *L. intracellularis*.

23. **(Previously presented)** The vaccine composition according to claim 20 wherein the isolated or recombinant polypeptide comprises the amino acid sequence set forth in SEQ ID NO: 1 or the amino acid sequence encoded by the SodC-encoding nucleotide sequence of pALK14 (ATCC 207155).

Claim 24 (Cancelled)

25. **(Previously presented)** The vaccine composition according to claim 22 wherein the immunogenic component comprises an isolated or recombinant polypeptide that comprises about amino acid residue 1 to about amino acid residue 42 of SEQ ID NO: 1.

26. **(Previously presented)** The vaccine composition of claim 25, wherein the immunogenic component consists essentially of about amino acid 1 to about amino acid 42 of SEQ ID NO: 1.

27. **(Withdrawn)** A combination vaccine composition for the prophylaxis or treatment of the infection of an animal by *Lawsonia spp.*, said vaccine composition comprising:

(i) a first immunogenic component comprising an isolated or recombinant polypeptide having at least about 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 1 or at least about 50% sequence identity to amino acid residues 1 to 42 of SEQ ID NO:1 or an immunogenic homologue or derivative thereof which is immunologically cross-reactive with *Lawsonia intracellularis*;

(ii) a second immunogenic component comprising an antigenic *L. intracellularis* peptide, polypeptide or protein; and

(iii) one or more carriers, diluents or adjuvants suitable for veterinary or pharmaceutical use.

28. **(Withdrawn)** A vaccine vector comprising a polynucleotide that encodes the immunogenic polypeptide of SEQ ID NO: 1, a homologue or a variant thereof operably linked to a promoter.

Appl. No. : 10/009,916
Filed : August 13, 2002

29. **(Withdrawn)** The vaccine vector of claim 28 wherein the polynucleotide comprises SEQ ID NO: 2 a homologue, or derivative thereof which has at least about 70% sequence identity thereto.

30. **(Withdrawn)** The vaccine vector of claim 28 wherein the *Lawsonia spp.* is *L. intracellularis*.

31. **(Withdrawn)** A polyclonal or monoclonal antibody molecule that binds specifically to a SodC polypeptide or a derivative of an SodC polypeptide from *Lawsonia spp.* wherein said derivative has at least about 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 1.

32. **(Withdrawn)** The antibody molecule of claim 31 wherein the SodC polypeptide or derivative thereof comprises the amino acid sequence set forth in SEQ ID NO: 1.

33. **(Withdrawn)** The antibody molecule of claim 31 wherein the SodC polypeptide or derivative thereof comprises about amino acid 1 to about amino acid 42 of SEQ ID NO: 1.

34. **(Withdrawn)** A method of diagnosing the infection of a porcine or avian animal by *Lawsonia intracellularis* or a microorganism that is immunologically cross-reactive thereto, said method comprising the steps of: contacting a biological sample derived from said animal with the antibody molecule of claim 31 for a time and under conditions sufficient for an antigen:antibody complex to form, and detecting said complex formation.

35. **(Withdrawn)** The method of claim 34 wherein the biological sample is selected from the group consisting of serum, lymph nodes, ileum, caecum, small intestine, large intestine, faeces or a rectal swab derived from a porcine animal.

36. **(Withdrawn)** A method of identifying a previous or current infection with *Lawsonia intracellularis* or a microorganism that is immunologically cross-reactive thereto, said method comprising:

contacting blood or serum from said animal with the immunogenic polypeptide of claim 1 for a time and under conditions sufficient for an antigen: antibody complex to form; and detecting said complex formation.

37. **(Withdrawn)** An isolated polynucleotide encoding a peptide, oligopeptide or polypeptide selected from the group consisting of:

Appl. No. : 10/009,916
Filed : August 13, 2002

(i) a peptide, oligopeptide or polypeptide which comprises an amino acid sequence which has at least about 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 1;

(ii) a peptide, oligopeptide or polypeptide which comprises an amino acid sequence which has at least about 50% sequence identity to amino acid residue 1 to about amino acid residue 42 of SEQ ID NO:1; and

(iii) a homologue or derivative of (i) or (ii) which mimics a B-cell or T-cell epitope of or confers immunity against a *Lawsonia spp* when injected into an animal.

38. **(Withdrawn)** The isolated polynucleotide of claim 37, wherein the peptide, oligopeptide or polypeptide comprises the amino acid sequence set forth in SEQ ID NO: 1 or about amino acid residue 42 thereof, or the amino acid sequence encoded by the SodC-encoding nucleotide sequence of pALK14 (ATCC 207155), or a B-cell epitope or T-cell epitope thereof.

39. **(Withdrawn)** The isolated polynucleotide of claim 38 comprising SEQ ID NO: 2, a complement or variant thereof.

40. **(Withdrawn)** The isolated nucleic acid molecule of claim 39 consisting essentially of the nucleotide sequence of SEQ ID NO: 2 or a variant thereof.

41. **(Withdrawn)** The isolated polynucleotide of claim 38 encoding from about amino acid residue 1 to about amino acid residue 42 of SEQ ID NO:2 or a variant thereof.

42. **(Withdrawn)** The isolated polynucleotide of claim 41 consisting essentially of that portion which encodes about amino acid residue 1 to about amino acid residue 42 of SEQ ID NO:2 or a variant thereof.

43. **(Withdrawn)** A method of detecting *Lawsonia intracellularis* or *Lawsonia spp* in a biological sample from a porcine or avian animal subject, said method comprising:

hybridizing one or more probes or primers from SEQ ID NO: 2 or a complement thereto to said sample; and detecting said hybridization .

44. **(Withdrawn)** The method of claim 43 wherein the biological sample is selected from the group consisting of: serum, lymph nodes, ileum, caecum, small intestine, large intestine, faeces and a rectal swab from a porcine animal.

45. **(Withdrawn)** The method of claim 44 wherein the detection is by any nucleic acid based hybridization or amplification reaction.

Appl. No. : 10/009,916
Filed : August 13, 2002

46. **(Withdrawn)** A probe or primer comprising least about 15 contiguous nucleotides from SEQ ID NO: 2 or the complement thereof.

47. **(Withdrawn)** The plasmid pALK13 (ATCC Accession No. 207196).

48. **(Withdrawn)** The combination vaccine according to claim 27 wherein the second immunogenic component is selected from the group consisting of OmpH, FlgE, hemolysin and autolysin.

49. **(Previously presented)** The vaccine composition of claim 23, wherein the isolated or recombinant polypeptide consists essentially of the amino acid sequence of SEQ ID NO: 1.